Diverse Perspectives:
Considerations About Embryonic Stem Cell Research

Indiana University Center for Bioethics
Stem Cell Study Group

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Abbreviations

AS cell	adult stem cell (also called "somatic" stem cell)
EG cell	embryonic germ cell
ES cell	embryonic stem cell
IU	Indiana University
IUCB	Indiana University Center for Bioethics
IUPUI	Indiana University – Purdue University at Indianapolis
IVF	*in vitro* fertilization
NBAC	National Bioethics Advisory Commission
SCNT	somatic cell nuclear transfer or "cloning"
SCSG	Indiana University Center for Bioethics Stem Cell Study Group

A. Introduction

Since the initial isolation of human embryonic stem cells in 1998 (Thomson et al. 1998), important developments in research have offered the promise of valuable therapeutic breakthroughs while continuing to raise significant social, ethical, legal and policy challenges. Among the interests of the Indiana University Center for Bioethics (IUCB) is a desire to engage issues of this kind, and in so doing, to provide a resource to the IU community, to Indiana, and to the entire country. The topic of stem cell research was, therefore, an appropriate one for discussion at the Center. In January 2002, the IUCB created a Stem Cell Study Group (SCSG). Our primary goal was to provide a forum for informed public discussion of the issues by making use of the considerable local scientific, legal and ethical expertise. In other words, we wanted primarily to educate ourselves about these issues. Our secondary goal was to identify and describe those points on which agreement could be achieved, as well as those issues on which agreement proved difficult if not impossible. This paper summarizes our efforts to meet both of these goals.

A.1. Methods of study

Study groups have been used on several occasions for engaging members of a community on topics related to bioethics. For example, study groups have been used to discuss single topics, such as advance directives (Singer et al. 1992) and research involving human subjects (Moreno et al. 1998). They have also been used for long-term collaboration on multiple topics (University of Illinois at Chicago Research Ethics Study Group 2002). Given considerable public commentary on the ethics, science and law related to human stem cell research, the IUCB concluded that a study group on these issues would be an effective way to raise awareness and understanding of this area of research.

The SCSG was open to the faculty and students of Indiana University (Indianapolis and Bloomington campuses) and, by extension, to others in the Indianapolis community. While this was meant to be inclusive rather than exclusive, we did not exhaustively recruit participants from outside the IU/IUPUI community, since facility space was limited. Email invitations were sent to related university departments but most participants from both inside and outside Indiana University reported that they had learned about the SCSG by word of mouth. Beyond this semi-structured recruitment effort, members of the group self-selected. There were no prerequisites for participation. On average, each meeting drew between fifteen and twenty participants, representing a diversity of fields. Regular attendees included medical, nursing and allied health professionals; individuals with legal and legislative experience; faculty from the schools of medicine, nursing and liberal arts; representatives of ethics services at local hospitals; and business professionals. While few members of the group had formal educational background in bioethics (e.g., advanced academic degrees), many had encountered such issues in their professional training or careers. Attendance was not mandatory, and we did not close the group to new participants at any time. We did have members join and leave at various points, but there was a core group of ten to fifteen participants who attended consistently for the duration of the study group. Many but not all of these participants are co-authors on this paper.

The SCSG met on a regular basis (approximately biweekly) at the IUCB from January until June 2002. Fifteen meetings were held, with each lasting between one and one-and-a-half hours. Six of the meetings were didactic sessions, at which an expert made a formal presentation for the first hour, followed by thirty minutes of discussion to clarify points. These six meetings covered the following topics: the science of stem cells; clinical applications; legal issues; ethical and policy issues; theological perspectives; and the distinction between the public and private sectors

(see Appendix A). A reading list was distributed for each of these sessions, and modest background reading was expected (see Appendix B). Nine meetings were devoted exclusively to group discussion without a formal presentation. At some meetings additional handouts were provided (e.g., covering recent news stories). Notes were taken at each meeting, including those at which formal presentations were made, to ensure that an accurate record of the discussion was maintained. The IUCB website (www.bioethics.iu.edu) listed the study group's objectives and schedule as well as related web resources. A moderated email distribution list provided an efficient means for dissemination of study group news and information, as well as a forum for discussion among group members.

A.2. Purpose of the paper

The purpose of this paper is to provide an accurate summary of the discussions and outcomes of the Stem Cell Study Group. In so doing, we intend to fairly represent the scientific, ethical, theological and legal analyses provided by our expert speakers as well as the richness and scope of the discussions. Not surprisingly, there was disagreement about many of these issues. In this sense we were no different from other committees and groups that have tackled issues such as cloning or stem cell research (NBAC 1997, 1999b; PCB 2002). Nevertheless, our efforts were far from fruitless, since they undoubtedly enhanced awareness of various thoughtful perspectives on human stem cell research. As education was one of the central objectives of the group, we intend for this paper to be useful to others who are seeking to understand the scientific, social and ethical implications of human stem cell research. This paper is set up in five sections: The Science of Human Stem Cells; Selected Ethical Issues; Theology and Stem Cell Research; Law and Policy Related to Stem Cell Research; and Conclusions.

B. The Science of Human Stem Cells

The Stem Cell Study Group heard presentations by two scientists at the Indiana University School of Medicine who have distinguished themselves in this area of research. The first speaker, who researches the property of plasticity in adult stem cells in mice, gave a summary presentation of the definition and properties of stem cells and how they are derived. The second, a pioneer in the field of umbilical cord blood transplantation, spoke about the current state of the research on embryonic and adult stem cells, including both advances and obstacles. He also described how certain existing therapies already make use of the peculiar capacities of stem cells, e.g. bone marrow and umbilical cord blood transplantation. This paper does not provide an exhaustive account of either presentation. Instead, we aspire only to provide an understanding of the fundamental science of stem cells: what they are, why they are important, and how they can be obtained.

B.1. What are "stem cells"?

Stem cells are cells that display the abilities (1) to self-renew (i.e., to divide and give rise to other stem cells) and (2) to produce offspring that develop each of the specialized functions of the body (e.g., blood cells, brain cells, heart cells, kidney cells, etc.) (NIH 2001, ES-2). In vertebrates, stem cells have classically been divided into two groups: *embryonic* stem cells and *somatic* or *adult* stem cells.

The fertilized oocyte (egg) is the "mother" of all stem cells. This single cell (the zygote) has the potential to form all the cells and tissues of both the embryo and the placenta, and it is therefore described as *totipotent*. After several rounds of cell division, at approximately the 64-cell stage, the cells form a structure called the *blastocyst*. One pole of the blastocyst consists of cells that will ultimately differentiate to form the placenta. The opposite portion contains the *inner cell mass*, which will go on to form the embryo itself. Cells

within the inner cell mass of the blastocyst are *pluripotent*. That is, each cell possesses the potential to give rise to all of the different kinds of cells in the human body. These pluripotent cells are referred to as *embryonic stem (ES) cells* upon growth in tissue culture conditions.

B.2. Why are "stem cells" important?

Because of their pluripotency and renewability, ES cells are believed to hold considerable promise for medical therapy particularly in the field of regenerative medicine. Since the first successful isolation of human ES cells in 1998, ES cells have proven to retain their self-renewal capacities *in vitro*. A single line of ES cells can be propagated for years, through several hundred cycles of replication, without compromising its genetic composition (IOM 2002, 32). Because of this remarkable proliferative capacity, a single healthy "line" of stem cells can provide a wealth of cells for use in research and/or transplantation. These properties also make the study of ES cells important for understanding early human development, especially the effects of cell mutations or chromosomal abnormalities on early embryonic development (NIH 2001, 17).

Moreover, since cultured ES cells are as yet undifferentiated, they retain the potential to develop into any kind of cell in the human body. Though research into specific differentiation pathways for human ES cells is still in its beginning stages, scientists have successfully induced mouse ES cells to develop *ex vivo* into the cells of various individual organ systems, including the brain and nervous system, the pancreas and the hematopoietic system (IOM 2002, 32). Moreover, if researchers can learn how to similarly "direct" human ES cells to differentiate into specific tissues, healthy cells from a single ES cell line may someday be used to repair damaged or defective tissue in patients with Parkinson's disease, Alzheimer's disease, cardiovascular disease, diabetes and spinal cord injuries, among many other debilitating conditions (IOM 2002, 8).

B.3. How can "stem cells" be obtained?

There are a number of sources for obtaining and isolating stem cells, each of which raises important ethical and policy concerns. The four most common sources include: aborted fetal tissue; embryos that remain after *in vitro* fertilization treatments; specially created "research-purpose" embryos; and mature (or "adult") somatic cells.

B.3.a. Embryonic germ (EG) cells from aborted fetal tissue

Of the two landmark scientific announcements related to stem cell research in 1998, one involved the extraction of *embryonic germ (EG) cells* from the gonadal ridge (the portion of a fetus that would develop into testes or ovaries) of a fetus following an elective abortion (Shamblott 1998). EG cells share many of the distinctive properties of ES cells, including the capacity for long-term self-renewal *in vitro* and the ability to give rise to multiple cell types of the human body (NIH 2001, 14). Federal and state legislation already permit the use of fetal tissue in transplantation research, so long as there are safeguards in place to ensure that the decision to terminate the pregnancy is separate from the decision to donate tissue for use in research (See Section E.1.a. below).

B.3.b. Embryonic stem (ES) cells from embryos that are in excess of clinical need for infertility treatments

Couples who utilize *in vitro* fertilization typically produce many embryos for possible repeat attempts. While there is variation among individual infertility centers in the number of eggs obtained, the number of eggs fertilized, and the number of embryos implanted, it is common for embryos to remain in excess of clinical need (New York State Task Force on Life and the Law 1998, 398-402). In the majority of centers, couples are given several options for the disposition of embryos that may remain after they

discontinue their efforts to get pregnant: they may donate the embryos to another couple for their own reproductive efforts, they may direct that the embryos be discarded, or they may donate the embryos for use in scientific research. In most cases, couples choose one of the latter options. In theory, then, no embryo may be used in research without express informed consent for this use (usually of the donor couple). Frozen embryos that are donated for use in research can be thawed and allowed to continue developing to the blastocyst stage, at which point the stem cells can be removed from the inner cell mass. This procedure results in the destruction of the embryo.

B.3.c. ES cells from embryos created for research purposes

While stem cells from existing embryos and aborted fetal tissue are useful, some scientists have argued that it would be of even greater value for researchers to create embryos specifically for research purposes. The creation of research-purpose embryos would ensure an adequate supply of embryos for research and treatment purposes, and it would also allow for maximum control over the genetic properties of the resulting stem cells, which is particularly important for transplantation and regenerative medicine.

In the past, embryos have been created for research by *in vitro* fertilization techniques, but recent discussion has been dominated by the prospect of using "somatic cell nuclear transfer" (SCNT or "cloning") as a means of creating embryos for stem cell research. In nuclear transfer, an oocyte's nucleus is removed, and a nucleus from a somatic cell is inserted into the enucleated oocyte. With the new nucleus, the egg has the full complement of chromosomes of a cell instead of the half complement that an oocyte usually contains. Thus, a sperm is not needed to contribute a second half complement of chromosomes, and the oocyte can be stimulated to become an embryo. The created embryo is then grown to the blastocyst stage, at which point the pluripotent cells can be extracted from the inner cell mass. The resulting stem cells are genetic clones of the cell from which the nucleus was obtained.

Some scientists have postulated that application of this technique could be revolutionary to human therapeutic organ repair, since it could provide a perfectly matched donor for every patient (Lanza et al. 2000, 3176). If a patient needs a kidney, for example, scientists may someday be able to direct ES cells cloned from that patient's own somatic cells to differentiate into kidney cells, creating a new organ that is an exact genetic match to the patient and therefore poses no risk of immunologic rejection. More imminent than the creation of whole organs is the possibility of using stem cells with the patient's own genetic code to regenerate damaged tissues (such as nerve tissue damaged by Parkinson's disease) or to match tissue for autologous cell replacement therapies. These applications fall into the category of treatments that have lately been labeled "therapeutic cloning." While promising, there are still many scientific issues to be addressed before the use of therapeutic cloning for the treatment of disease can be considered a realistic possibility (Lanza et al. 2000, 3175).

B.3.d. Adult stem cells

In adult human beings cell division is constantly underway, providing the body with renewable sources of cells that naturally die. The replacements for the body's cells come from relatively undifferentiated cells that are programmed to generate specific types of cells. These *adult* or *somatic* stem cells (AS cells) are *multipotent* cells—like embryonic stem cells, they have the ability to self-renew, but their progeny can give rise not to all the different types of cells that comprise the human body, but to all the different types of cells that comprise a particular tissue or organ (e.g., all of the cells of the blood, heart, liver or brain) (Blau et al. 2001). The principal sources of somatic stem cells include

bone marrow, cornea, retina, brain, skeletal muscle, dental pulp, skin, pancreas, liver, and the lining of the intestine.

The hematopoietic stem cell is probably the best-characterized stem cell in the human body. These cells divide slowly in the bone marrow and replenish themselves throughout life. Every hour, 10 billion red blood cells and 100 million white blood cells are produced in the marrow from hematopoietic stem cells and are released into our circulating blood. Sources of hematopoietic stem cells already in use for transplantation to treat a number of malignant and non-malignant diseases are: bone marrow, growth factor mobilized-peripheral blood, and umbilical cord blood (NIH 2001, 46).

There has long been considerable interest in the concept of adult stem cell *plasticity*—the capacity of a cell to generate cells of a completely different organ upon transplantation (Orkin 2000, 1212). Recall that adult stem cells are specific to one organ or another. There are heart adult stem cells, brain adult stem cells, blood adult stem cells, etc. However, it may be that adult stem cells of one organ type have the ability to give rise to cells of another organ. A number of studies have reported that adult stem cells possess such *plasticity*. Bone marrow cells have been demonstrated to give rise to muscle cells, brain stem cells have contributed to blood and muscle, and so on (Howell et al. 2002; Jiang et al. 2002).

However, whether or not adult stem cells truly possess plasticity is still far from certain. Scientists have shown that adult stem cells from one organ can take on the *appearance* of cells from another organ, but they have yet to definitively prove that the transformed cells have also assumed the *function* of the new organ (Holden and Vogel 2002). Much research remains to be done to prove that adult stem cells have the type and extent of plasticity found in ES cells.

C. Selected Ethical Issues

It is not surprising that ES cell research raises challenging questions, given that it touches on ethics, religion, culture, and fundamental social practices. Certain important ethical questions are raised by any new resource-intensive technology. For example, what weight should the government and its regulatory structure give to new, expensive technologies relative to other important social priorities, such as the provision of basic health care? How should society direct communal resources toward those therapies that promise benefit for all members of society? How should society support the use of a particular technology for valuable therapeutic purposes but restrict its use for less acceptable ends? How should such distinctions to be made?

Another set of important ethical and policy issues is specific to scientific research on human tissues generally, most notably the issue of informed consent. What kind of informed consent should be sought for ES cell research, and from whom? How should the risks and potential benefits be described? Additional issues relate to the treatment afforded and respect given to the body and its parts, to the products of conception, and to life itself (NBAC 1999a).

Many studies and thoughtful analyses have discussed these issues in considerable detail (AAAS/ICS 1999; AJOB 2002; IOM 2002; NBAC 1999b, 2000; NIH 2001; NCB 2001; PCB 2002). Although each was undertaken at a particular time, with access only to the current scientific knowledge, similar ethical issues arose in every instance. Our experience was no different. We take this to mean that in an area of technology such as this, there are a number of enduring ethical issues that transcend the science.

The issues that proved to be central to our discussion were those arising from the nature of the various sources of ES and EG cells: what ethical concerns do the sources raise, and to what extent ought society to limit, permit or facilitate

the various methods to obtain these cells? Since the purpose of this paper is to accurately represent the context and content of our SCSG discussions, we will focus on these questions.

C.1. EG cells from fetal tissue following abortions (cadaveric fetal tissue)

The use of fetal tissue following abortion raises issues that warrant public scrutiny irrespective of whether one finds abortion to be morally objectionable or permissible. Like others who have commented on this issue, we heard different points of view regarding the association of research using EG cells obtained from cadaveric fetal tissues with abortion. Though a direct *causal* relationship is difficult to demonstrate empirically—i.e., that the prospect of donating fetal tissue for EG cell research would cause women to have abortions who otherwise would not—safeguards already exist in federal fetal tissue transplantation regulation (see section E.1.a. below) to reduce the risk that a woman's decision to abort would be inappropriately influenced by the possibility of donating fetal tissue for transplantation. A more general, but nevertheless more difficult, concern is the *symbolic* association some perceive between the use of cadaveric fetal tissue and the abortion itself. On this view, benefiting from the product of a moral wrong may be conceived as legitimizing the original wrongdoing.

Members of the SCSG voiced broad approval for the use of cadaveric fetal tissue as a source of embryonic germ cells. While a few members did object to any practice that may increase the incidence of abortion or enhance its social acceptance, it was nevertheless agreed that the collection of EG cells from an already-deceased fetus is, in itself, less ethically problematic than the deliberate destruction of an embryo for the same purpose, provided the possibility of donating tissue in no way encouraged the decision to abort. Nonetheless, even among those who supported the use of aborted fetal tissue, it was believed that existing procedural safeguards separating the decision to abort and the decision to donate; prohibiting incentives for the donation of fetal tissue; and prohibiting directed donation ought to be strictly enforced.

Consent for the donation of fetal tissue proved to be more problematic. We considered the scenario to be more analogous to the donation of a deceased family member's tissues or organs, than to a case of third-party "consent" in the traditional medical research model, since there is no living individual who could be considered a "subject" of the research. And yet there remained some disagreement about who has the right to consent to that donation. Some SCSG members identified strongly with the position held by Burtchaell that a mother who decides to abort her child abdicates her parental responsibilities and therefore forfeits her parental right to determine the disposition of the dead fetus (Burtchaell 1988, 8). However, many others believed that the decision to donate fetal tissue should be the mother's, since our society recognizes the authority of family members to donate a decedent's organs for transplantation, even if the same family members authorized the withdrawal of life-sustaining treatment.

C.2. ES cells from human embryos

The potential for therapeutic benefits arising from ES cell research constitutes a powerful case for supporting this area of scientific endeavor. Yet, even if society supports ES cell research in principle, important ethical issues about the use of embryos as a source for ES cells must be addressed before this support can translate into practice. For example, it is well known that a coherent regulatory scheme does not exist for infertility clinics in the U.S. (New York State Task Force on Life and the Law 1998, 407-417), making it difficult to establish common standards for obtaining, storing, freezing, donating and discarding embryos, and for making them available for research. This regulatory vacuum raises questions about how this particular source of embryos can be adequately monitored. These

concerns are already in need of considerable attention from ethicists and policy-makers, and they are only becoming more crucial as science continually makes strides in stem cell research.

Prior to questions of regulation and protocol, however, even more profound moral issues must be addressed, and it was on these fundamental ethical concerns that the SCSG focused. Chief among these concerns is that the isolation of embryonic stem cells for use in research requires the destruction of an embryo in the blastocyst phase of development. The permissibility of ES cell research thus depends upon the permissibility of destroying an embryo, and much of the debate surrounding the issue derives from the question: how should the human embryo be treated? Like other groups, the SCSG did not come to unanimous agreement on this issue. However, we did make considerable progress towards understanding the complexities of the various positions and developing a common understanding of what is at stake in making policy decisions of this kind.

To say that something "has moral status" is to say something about how one should act toward that thing or person and what that thing or person may expect from others (NBAC 1999b, 49). Thus, to take a position on the moral status of embryo is to make an argument about how it ought to be treated—by its parents, by researchers, and by society as a whole. So it is not surprising that views diverge widely, ranging from those who believe that the embryo has "full" moral status (that is, equivalent to an adult human) to those who believe that the embryo has no greater moral status than a cluster of cells, with various intermediate positions between. Each of these views has very different implications for public policy. For example, if those who hold the "full moral status" position believe that beings with this status cannot be destroyed under any circumstance, then they cannot support ES cell research. The *potential* benefits to others should be knowingly foregone in favor of the protection of the embryo. A "developmental" view, such as that adopted by NBAC, holds that the embryo deserves "respect" as a form of human life, and that the moral status of the embryo increases in relation to its developing state (NBAC 1999b, 50). While this view attempts to provide the basis for both permitting ES cell research and demonstrating respect, it does not establish when it would be permissible to destroy the embryo and at what point in its development it would become impermissible.

The issue of the treatment of the embryo is rooted in beliefs about the beginning of life and the nature of human personhood. Thus, it is not surprising that the SCSG did not come to unanimous agreement on the issue. Answers to such fundamental questions are often based on metaphysical or theological presuppositions that are essentially unverifiable and, as such, incommensurable. To some members of the group, this issue seemed to be an example of what Alasdair MacIntyre calls an "interminable debate" (MacIntyre 1981, 6). Recognizing the pitfalls of the conventional rhetoric, we struggled for alternative ways of considering the issue.

One way that we made progress was by considering the following thought experiment: Would we treat pregnancy differently if we considered the products of conception to have full moral status as human persons? How could society endeavor to provide the same degree of protection for embryos as it provides for infants and small children? Would we require pregnant women to refrain from consuming alcohol, cigarette smoking, or engaging in risky diets? Would we impose criminal penalties upon those who violated these mandates, as we do for those parents who fail to use car seats or who otherwise neglect their children? Would we require them to take affirmative steps to ensure the health of the developing baby by taking vitamin supplements and consuming at least five servings of fruits and vegetables per day? Moreover, considering that at least 50% of conceptions result in miscarriage before the woman even

knows she is pregnant, would we require these measures of all women of childbearing age and capacity, just in case they are pregnant?

This hypothetical proved a provocative tool for discussion, as it compelled group members to take the issue of "moral status" out of the abstract and to consider its real implications. Many members of the SCSG believed that to answer affirmatively to any of the above questions would impose unreasonable sacrifices and restrictions on the women who are carrying those embryos. We could not require women to take as extensive measures to care for embryos as we require them to take for their children, and it seems equally ludicrous to expect people to treat every early spontaneous abortion—many of which go undetected—as if it were equivalent to the death of a fully-grown child. In short, to treat the embryo as having the moral status as an adult human being would negatively impact the role and status of women in our society.

Other SCSG participants did not agree that granting embryos full moral status would necessarily result in such harsh restrictions or extreme expectations. Society already takes affirmative measures to promote fetal health and prenatal care. Women who know they are pregnant—if they want the child—usually do change their behaviors to protect their fetuses. Society has been known to go as far as putting a drug-addicted pregnant woman in jail to prevent her from harming her fetus. Furthermore, some women do mourn embryos lost in early spontaneous abortion, provided they knew they were pregnant. And even if the embryo has full moral status, it does not necessarily follow that we would expect all women of childbearing age to alter their behaviors on the chance that they might be pregnant. People are free to engage in all sorts of behaviors that they know to have a small chance of harming someone unknown to them. The only behaviors that would necessarily be forbidden if the embryo were to be granted full moral status would be its deliberate harm or destruction, as in abortion or the extraction of ES cells, and some members of the SCSG did not see abstinence from those activities as extraordinary burdens.

In the end, the thought experiment elicited the same diversity of opinions seen in contemporary debates among ethicists, legislators and the general public. To that extent, our deliberations certainly supported the impression that the issue may well be irresolvable at a metaphysical level. At the same time, the SCSG discussions confirmed the importance of the moral status of the embryo in the current debate about ES cell research. Few issues elicited positions as earnest or as deeply felt as the status of the embryo, and no other issue commanded as significant a share of our discussion time.

The very prevalence of this issue led us to the important insight that one does not have to ascribe "full moral status" to the embryo to be concerned with its treatment. How we treat the embryo reflects (and possibly influences) our collective senses of self, personhood, body and society. In this respect, it is similar to other defining social practices (e.g., marriage, adoption, childrearing, child abuse, commerce in organs, commerce in embryos, oocytes and sperm, abortion and disposal of the dead), for which society has traditionally exercised particular care through legislation and regulation. Thus, like many other groups considering this issue, the SCSG had less difficulty agreeing that an embryo deserves some measure of respect than determining what that respect entails in relation to the treatment of embryos remaining after infertility treatments or the creation of research-purpose embryos.

C.2.a. Embryos in excess of clinical need following infertility treatments

Support for research on ES cells from embryos in excess of clinical need following infertility treatments often relies on the argument that the embryos would otherwise be discarded. As such, the SCSG considered how the moral status of an

embryo is or could be affected by the fact that it will never be implanted in a woman's uterus with the intention of it becoming a child. How might the destruction of that embryo be different from the destruction of an embryo that will be implanted?

When stem cells are taken from the inner cell mass of a blastocyst, the embryo is destroyed, and so a life (or potential life) is ended. In a sense, though, the "killing" of an embryo that remains after infertility treatments is unlike any other kind of killing, inasmuch as there is no loss of life that would otherwise have existed. If the embryo were not used for stem cell research, it would not develop into a fetus and then a child, but would remain frozen until eventually discarded. By contrast, when an adult person is killed, a life that would otherwise have continued to exist is ended. Decades of life may have been lost. This is true even for someone who is terminally ill. The individual would have died anyway if her life had not been ended intentionally, but an indeterminate amount life that would otherwise have existed—whether a day or a year—has been taken away. In short, one may consider the taking of life to be wrong not simply because a life is ended, but because life is lost that would otherwise have existed, and therefore condone the destruction of frozen embryos that remain after infertility treatments.

Some members of the SCSG raised concerns about this analysis, however. To these members it seemed problematic to make the value of any being conditional on a probability of what will be done to it in the future by others. Not only is such a position dangerous (inasmuch as it invites all manner of violations of persons who are "going to die anyway"), but it also undermines any notion that the "moral status" of the embryo derives from something inherent in the embryo itself as a human life. If we are to ascribe any degree of "moral status" to the embryo on the basis of what it *is* (or even on what it has the internal potential to *become*) then it must inhere equally to all embryos, regardless of external contingencies. If one bases an embryo's value on what others plan to do with it, then "moral status" becomes nothing more than a measure of social utility.

But it would be misleading to characterize the discussion within the SCSG as a contrast between those who believed that obtaining ES cells from embryos remaining after infertility treatment is ethically permissible because the "killing" of an embryo is acceptable and those who believed that this act is not acceptable. Embryo destruction is a consequence of obtaining ES cells from this source. For some members of the SCSG, no amount of potential benefit from ES cell research would justify this means of obtaining them. For others, the degree to which this is ethically justifiable depends as much on the purpose and intention of the use of the ES cells as on the manner of obtaining them. And for still others, it does not seem inconsistent to object to embryo destruction while still supporting research on ES cells that have already been obtained from this source. This position is very similar to a dilemma described by Father Demetrious Demopolous, who explained an Eastern Orthodox perspective on this issue in testimony before NBAC:

> I cannot condone any procedure that threatens viability, dignity and sanctity of that life. In my view the establishment of embryonic stem cell lines…was done at the cost of human lives.

When asked how this view applied to the use of existing ES cell lines, Father Demopolous replied that:

> …I wish they had not been derived in the way that they were but since they are there…I do not think it would be a good thing not to take advantage of [their availability]. (NBAC 1999b, 54)

As noted below in Section E.1.d., this type of argument informed the present policy of the Bush administration.

C.2.b. Embryos created solely for research purposes

Arguments in favor of intentionally creating embryos generally rely on two points: first, that there may not be an adequate supply of ES cells from existing embryos; second, that the scientific quality of these embryos may be superior to those that are destined to be discarded by IVF clinics. Nevertheless, the idea of creating embryos specifically for use in research has provoked some of the strongest opposition of all the sources of ES cells.

Most who oppose the destruction of embryos remaining after infertility treatments also oppose the intentional creation and destruction of "research-purpose" embryos on similar grounds, with the additional objection that it further "instrumentalizes" human life. There is also a significant group of people who support ES cell research using embryos remaining after infertility treatments, but who draw the line at the creation of research-purpose embryos. To these individuals, the intention of the person who created the embryo has critical moral relevance: it is one thing to create an embryo for the purpose of having a child, which would thus have at least a chance of growing to adulthood, and later to donate it for research when it no longer has that chance; it is quite another thing to create an embryo for the express purpose of obtaining ES cells, knowing that this procedure will destroy the embryo. This position reflects the same moral intuition against instrumentalization – using something or someone purely as a means to an end. Even among SCSG members who did not believe that frozen embryos have the same moral status as adults, many believed that intentionally creating an embryo solely to obtain ES cells called into question whether *any* respect is accorded to that embryo. And of course, for those members who believed that the frozen embryo has little or no moral status, the idea of producing embryos to obtain ES cells was not morally problematic.

All SCSG participants recognized the distinction between the use of embryos remaining after infertility treatments and the creation of "research-purpose" embryos for the purpose of obtaining stem cells. However, opinions varied as to the ethical or policy relevance of that distinction. There were some who believed both uses to be illicit; some who believed that the use of embryos that were destined for destruction anyway should be allowed, but not the creation of embryos specifically for research purposes; and some who could conceive of circumstances under which even the creation of embryos for research may be justified.

C.3. ES cells and cloning

Our discussion took place against the backdrop of federal and state legislative debate on the subject of human cloning. While we did not consider the issue of cloning systematically, we did discuss the potential benefits and concerns associated with the possibility of using of somatic cell nuclear transfer (SCNT) technology to create embryos for use in stem cell research and therapies.

Unlike human reproductive cloning, the creation of embryos by nuclear transplantation for the purpose of extracting their stem cells would not involve implantation of an embryo in a uterus and thus would not produce a fully developed, live-born person, i.e., a "clone". Rather, like embryos created by IVF for research (rather than reproductive) purposes, embryos created by what is commonly called "*therapeutic*" (rather than reproductive) cloning would only be grown to the blastocyst stage, at which point ES cells would be extracted from the inner cell mass, destroying the embryo.

By using stem cells from an embryo created by SCNT with the transplant recipient's own genes, scientists could create tissue that the recipient's body would not view as foreign. This could greatly reduce the likelihood that a person's body would reject that tissue and could therefore obviate the need for immunosuppressive drugs.

It is widely believed that this development could revolutionize treatment of such devastating diseases as Lou Gehrig's disease, Parkinson's disease, Alzheimer's disease, spinal-cord injury, cancer, cardiovascular diseases, diabetes, rheumatoid arthritis, and many others.

Given these considerations, some members of the SCSG expressed concern that legislative action undertaken to ban human reproductive cloning should not extend to the use of nuclear transplantation to produce embryos for stem cell research and therapy. These members held that it is not cloning technology in itself that is unethical, but rather the use of such technology for procreative purposes. The use of nuclear transplantation in stem cell research and, ultimately, regenerative medical therapies could potentially save millions of lives and relieve the suffering of countless others, and many people therefore believed that it should be permitted. Not surprisingly, this group did not include those members of the SCSG who objected to the destruction of embryos for ES cell research.

D. Theology and Stem Cell Research

As noted above, ES cell research raises fundamental questions about the moral status of incipient human life, answers to which vary widely and depend largely on one's metaphysical presuppositions. For many people, such beliefs are rooted in the teachings of a particular theological tradition. In light of the profound influence that religious traditions have had and continue to have on ethics and public policy discourse about this and other issues, the SCSG devoted one of its meetings to presentations and discussion of two theological perspectives.

Certainly, no single religious point of view exists on the issue of human stem cell research. Indeed, not only is there considerable diversity among faith traditions about some of the issues associated with stem cell research, but there is also disagreement within individual faith traditions on many of these issues (NBAC 2000). The SCSG heard presentations from a Roman Catholic priest and a congregational Jewish rabbi. The selection of these perspectives was determined by the availability of speakers and the interests of SCSG members. Other important faith traditions have strongly held views about stem cell research, and while the SCSG schedule did not permit presentations of all of these perspectives, we suspect that they would similarly have enriched the discussion (as would additional legal, ethical, or scientific commentaries).

Both the Jewish and Catholic traditions work from stable Biblical and theological points of view. Both traditions have clear orthodox perspectives, which they offer within the public arena. Both traditions seek clear, reliable, and logical propositions to guide behavior (Cahill 2001, 47-48). And yet their conclusions, prohibitions, and sanctions differ dramatically. Thus, these two presentations offered instructive similarities and contrasts, provoking reflection on method in religious ethics and about the place of religious discourse in public policy.

Like other presentations the SCSG heard, the descriptions that follow reflect the views of the presenters, rather than the group as a whole. Still, given that religious claims about the moral life are foundational for many cultures, those descriptions can only be seen as basic descriptions of detailed moral theologies. The sections that follow were written principally (with only modest editing for consistency) by Rabbi Dennis Sasso and Father Joseph Rautenberg, respectively.

D.1. A Jewish perspective

Judaism is a "life-affirming" faith. The protection and improvement of life is a divine imperative based on the biblical command: "Choose life" (Deuteronomy 30:19). The commandments in the Torah are given for the purpose that we may "live by them" (Leviticus 18:5). Under all circumstances, we are bidden to protect life. One may only sacrifice one's own life under

extraordinary circumstances, e.g., if one is forced to commit murder, idolatry or sexual immorality (Babylonian Talmud, Sanhedrin 74a and Pesahim 25a-b; Shulhan Arukh, Yoreh Deah, 157:1).

A preeminent Jewish value is to "provide healing." God is often referred to as Rofeh "healer" or "physician" (Daily Amidah, 8th blessing). The Jewish morning liturgy begins with a blessing of marvel at the human organism and gratitude for its creation. Following this there is a prayer of thanksgiving for the soul, which animates the body. Given the importance of healing, physicians and health providers are seen as partners of God. This therapeutic orientation provides the basis for the Jewish teaching on the issue of stem cells.

Any discussion of research involving stem cells evokes questions about the beginning of life. In the Talmud and rabbinic writings the embryo and fetus are seen as limbs, as extensions of the life of the mother (Rosner 1978, 257-259). While the fetus is potential human life and deserving of special moral consideration and protection, it is not regarded as independent human life; it is a part of the body of the mother and has no "legal" status of its own. Thus, in issues such as abortion, the presumption is always in favor of the mother. Jewish religious law permits abortion whenever the pregnancy poses a threat to the physical or, according to some interpretations, to the psychological well-being of the mother (Feldman 1986, 79-90).

This earliest source of this teaching is found in the Torah, in which a different punishment is assigned for the killing of a fetus and the murder of its mother (Exodus 21:22). Later, in the rabbinic tradition, it was taught that if a woman has life-threatening difficulty in childbirth, the child should be aborted (Mishna, Oholot 7:6). Once its head has emerged, however, it may not be harmed. The Talmud explains that the embryo may be seen as a "pursuer", and one is justified in defending one's life against a pursuer [This argument is based on two scriptural passages: Deuteronomy 25:11-12 and Leviticus 19:16. See Maimonides, Mishne Torah, Hilchot Rotzeach Ush'mirat Hanefesh, ch. 2, par. 6; Karo, Shulhan Arukh, Hoshen Mishpat, ch. 425, par. 2].

While the Talmud briefly discusses the issue of ensoulment, it dismisses it as ultimately unanswerable (Babylonian Talmud, Sanhedrin 110b). According to accepted Jewish teaching, the soul enters at birth, and this matter is irrelevant to the question of abortion, since the life and health of the mother are the issues at stake.

The issue of stem cells is different from the issue of abortion, inasmuch as the embryo is not developing in the womb. According to Jewish tradition, "genetic material" outside the womb has no legal status. Even within the womb, up until forty days, it is considered to be the equivalent of water (Dorff 2000, C-4).

In addition to its "pronatalist" stance, Judaism sees technology as neutral. Technology is not good or bad in itself; what matters is how you use it (Dorff 2002, 31). There is no "natural law" in Judaism. Jews neither worship nor degrade nature. God created the world incomplete, with much left to be done. As partners of God, humans are the appropriate actors in the completion of creation. Accordingly, even Orthodox Jewish leaders have endorsed therapeutic cloning as a means of obtaining stem cells for research and medical therapy (Cooperman 2002, A04).

D.2. A Catholic perspective

The Catholic Church teaches that it is not licit to produce or destroy human embryos for the cultivation of human stem cells and it is not licit to use such stem cells provided by other researchers (Pontifical Academy for Life 2000). This teaching is rooted in beliefs about who or what the embryo is (ontological status), what obligations are owed to that being (moral status),

and how one ought to behave in situations of uncertainty (epistemology).

In syngamy, the sperm and oocyte unite to become a new human organism, genetically distinct from either of its parents. The zygote (and later the embryo) is an individual human being with its own internal dynamic, its own end. It is an actual human life in the process of development, not a being that might someday "become" a human life. This new human being has its own ontological status. It depends on its mother, but is not "part of her": "the living human embryo is – from the moment of the union of the gametes – a *human subject* with a well-defined identity, which from that point begins its own *coordinated, continuous and gradual development*, such that at no later stage can it be considered as a simple mass of cells" (Pontifical Academy for Life 2000, *emphasis in original*).

A "developmental" view holds that the embryo does not start out fully 'personal' but becomes more and more a person as it goes through certain developmental stages approaching birth. This seems to be an intermediate or compromise position that reflects abortion law in the United States. Such a view is held by some moralists within the Catholic Church (Shannon and Wolter 1990). The problem a developmental view has is in identifying any equally significant watershed point after conception after which the being could be said to have become a "person." Before conception, there exist two 'things': the mother's egg and the father's sperm. After conception, there exists a new human being, developing according to its own unique interior principles. In the process of that being's development, there is no comparable point of physical change on which to hang such a significant ontological distinction. Moreover, by hinging "personhood" on certain characteristics or faculties that appear at some point in the development of the new being, the developmental view raises questions about the "personhood" of adult (or child) human beings who lack or lose such "critical characteristics" (e.g. those who are in a permanent vegetative state or profoundly mentally disabled, etc).

Ontological and moral status are linked. Who or what the embryo is physically is linked to who or what it is morally, and what obligations we have to it. This is an intrinsic, not an extrinsic, link. Thus, the embryo's ontological status as a human individual entails full moral status as a human person: "From this it follows that as a "*human individual*" it has the *right* to its own life; and therefore any intervention which is not in favor of the embryo is an act which violates that right…" (Pontifical Academy for Life 2000). There is an intrinsic sacredness and dignity in the human person – at all stages of its development – that is not dependent on any social or legal ascription of "respect," even by her or his mother. As such, no individual life (including embryonic) may ever be sacrificed by another for the greater good of society (scientific progress toward the treatment of disease). Our society purports to treat all human beings as fundamentally equal in dignity and under the law. This status is ascribed all at once and independent of rational function, or any other qualitative criterion. The Catholic Church sees no basis for the exclusion of the embryo from this full human dignity and equality.

The Catholic Church recognizes that human beings have moral obligations to heal and to rescue others, and that the moral difference between action and omission can be slippery and variable. Nevertheless, it is generally accepted that a morally significant difference exists between (1) killing an individual human being intentionally and in a causally immediate way, and (2) allowing a human being who is causally/physically remote from us to die. For example, most people would recognize a moral difference between intentionally killing another and declining to make an additional contribution to charity, even if it is theoretically foreseeable that the latter act would result in increased loss of life somewhere in the world. Similarly, a researcher's obligation to refrain from directly killing human beings for stem cell research should

prevail over his or her responsibility to pursue one particular means possibly to rescue people through such research. Our moral, existential, character-forming responsibility for the killing of embryos for their stem cells determines our decision not to help in this way. This is not a rejection of the value and dignity of human persons, but a rejection of *one particular means* of responding to that value, while affirming and pursuing other means. The destruction of the embryo associated with harvesting stem cells is, by contrast, an inevitable devaluing of the human being 'harvested.'

How can the Catholic Church claim to "know" the ontological or moral status of the embryo? Beyond the biological facts, Catholic Christianity, like Judaism and all other religious and moral traditions, relies on fundamental intuitions, vision, stories and narrative ("You formed my inmost being; you knit me in my mother's womb" -- Psalm 139:13). This is one reason that the debate in the public arena may well be "interminable" (MacIntyre 1981, 6). We may have fundamentally different stories or "forms of life." In the public sphere, the more relevant determination may well be how we ought to act in a situation of uncertainty or of irreconcilable disagreement. While Catholicism, like Judaism and other traditions, affirms the role of human beings as co-Creators and consequently embraces the use of technology in service of human persons, the Catholic Church also acknowledges that human ingenuity can overreach its appropriate boundaries. An innovation that seems promising in the immediate future can have unanticipated destructive effects in the long run. Given the uncertainty about the risks of this research and the disagreement about its morality, the Catholic Church has urged policy-makers to "err on the side of life." If it cannot be shown that the embryo is *not* a human person, then we ought to treat it with the respect owed to a full member of the human community. The risks of not doing so—the potential for widespread destruction of human lives and the moral degradation of a society that so disvalues human life—are simply too great.

These individual harms and societal risks become even less acceptable when one considers that the medical benefits promised from embryonic stem cells may also be available through adult stem cell research. Why risk possible harm to human persons if this may be unnecessary? It may be argued that it would be quicker to do both embryonic and adult stem cell research, and that lives may be lost or damaged in the time spent establishing what, if any, are the limits of adult stem cells as compared with embryonic. However, it may be equally possible that progress toward useful therapies would, in fact, be more rapid if we did not divide our efforts but focused on the more generally morally acceptable research on adult stem cells, at least until this is shown to be unsatisfactory.

The preceding sections on "Selected Ethical Issues" and "Theology and Stem Cell Research" reflect and illustrate the level of discussion we had about a number of challenging moral issues. These conversations were exhaustive but not comprehensive: some issues (such as 'moral status') occupied a considerable amount of our time, while others received less attention. Both approaches helpfully informed the SCSG.

E. Law and Policy Related to Stem Cell Research

E.1. What does the law say?

E.1.a. EG cells from cadaveric fetal tissue

Obtaining stem cells from aborted fetuses is permitted under federal regulations for the protection of human subjects in research, specifically 45 CFR 46.206: "Research involving…cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities." The regulation adds procedural safeguards to separate

the decision to donate tissue from the decision to abort:

> "(h) No inducements, monetary or otherwise, [can] be offered to terminate a pregnancy; (i) Individuals engaged in the research [may] have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and (k) Individuals engaged in the research [may] have no part in determining the viability of a neonate." (45 CFR 46.204)

Within these parameters, state laws vary. Some states prohibit all research on aborted fetuses and/or the tissue of aborted fetuses (e.g., Indiana [Ind. Code § 16-34-2-6 (2002)], Arizona [Ariz. Rev. Stat. § 36-2302 (2001)]), while others prohibit research on aborted fetuses only if the woman's consent is not obtained (e.g., Massachusetts [Mass. Ann. Laws ch. 112, § 12J(a)(II) (2002)], Tennessee [Tenn. Code Ann. § 39-15-208(a) (2001)]). About half the states do not address the issue at all. In the absence of a statute prohibiting fetal research, it is permitted.

Federal law not only permits fetal tissue research and transplantation, it also funds therapeutic uses of fetal tissue. The NIH Revitalization Act of 1993 permits federal funding for the "transplantation of human fetal tissue for therapeutic purposes," as long as a number of conditions are satisfied (e.g., practices are consistent with state law, woman's decision to abort is made before tissue donation is requested, method or timing of abortion not affected by decision to donate tissue) (42 USC §289g-1).

E.1.b. ES cells from human embryos

Though no federal laws address the use of embryos *ex utero* in research, some states do prohibit use of embryonic stem cells for research and/or transplantation. Louisiana requires that embryos be used only for implantation to have a child [La. Rev. Stat. 9:122 (2002)]; Arizona bans experiments with any embryo or parts of an embryo [Ariz. Rev. Stat. §36-2302(A) (2001)]; and several states (including Massachusetts and Rhode Island) ban research on a live embryo "before or after expulsion from its mother's womb" [Mass. Ann. Laws ch. 112, §12J(A)(I) (2002); R.I. Gen. Laws § 11-54-1(b) (2001)]. (There is some debate about the applicability of these laws to embryos that were never intended to be transferred to a mother's womb.)

There is also a body of state law governing the sale of human embryos, which may apply to the sale of stem cell lines derived from human embryos. Some states prohibit sales of embryos for any purpose (e.g., Louisiana [La. Rev. Stat. 9:122 (2002)]); some prohibit the sale of embryos for research purposes (e.g., North Dakota [N.D. Cent. Code, § 14-02.2-02 (2002)], South Dakota [S.D. Codified Laws § 34-14-17 (2001)]); and still others prohibit the sale of embryos for any purpose, but permit the sale of cell lines derived from nonliving embryos (e.g., Minnesota [Minn. Stat. § 145.422 (2001)]).

E.1.c. The Clinton administration policy

Federal policy toward the facilitation of embryonic stem cell research has been much more explicit. For the past eight years, annual riders in appropriations bills funding the National Institutes of Health (NIH) have prohibited use of federal funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed (Passeggio 2002, 347-349). Under the Clinton administration, these prohibitions were interpreted in such a way that federal research support could be provided to researchers to *use* ES cells, but this support could not be provided to researchers to *derive* ES cells from embryos. Derivation—obtaining and culturing ES cells from the inner cell mass of the blastocyst—destroys the embryo and would therefore violate the prohibition on the use of federal funds as defined in the riders.

This interpretation, provided by the Office of the General Counsel of the Department of Health and Human Services was based on the argument that an ES cell is not itself an embryo (Kukla 2002, 508). Placed into a uterus, a single stem cell could not develop into an adult human being. The legal opinion did not apply to privately funded researchers, who were still free to develop embryos and obtain ES cells from them (Kukla 2002, 509). It was on this basis that the National Institutes of Health developed a proposed policy for stem cell research, one that would have permitted grantees to use ES cells but not to develop these cell lines themselves.

The ethical distinction supporting the policy drew criticism from both sides of the issue. Federal funding of ES cell research would create a considerable demand for new cell lines, opponents argued. The government would be causally complicit in the destruction of embryos to meet that demand, whether or not it directly funded the destruction. Meanwhile, proponents of ES cell research stressed that the quality of the science would be enhanced if the same researchers could both collect and study the cells. The NIH position, while appearing to take a middle road, was seen by some as ethically disingenuous, since it would support a worthwhile goal (ES cell research) but not the means necessary to carry it out (funding the derivation). Implementation of the proposed NIH guidelines was put on hold as a result of the change from the Clinton to the Bush administration.

E.1.d. The Bush administration policy

The change in administrations meant that the proposed NIH guidelines remained in policy limbo. On August 9, 2001, President Bush described his policy approach. President Bush's policy would permit federal funding for research involving existing stem cell lines (approximately sixty) but prohibit federal funding for any research involving new stem cell lines, regardless of where the destruction of the embryo takes place (Kukla 2002, 515). Specifically, Bush's policy allowed federal funding for existing stem cell lines that were derived: (1) with the informed consent of the donors; (2) from excess embryos created solely for reproductive purposes prior to August 9, 2001; and (3) without any financial inducements to the donors. The policy denied federal funding for: (1) the derivation or use of stem cell lines derived from newly destroyed embryos; (2) the creation of any human embryos for research purposes; or (3) the cloning of human embryos for any purpose (The White House 2001).

E.2. What should the law have to say about using stem cells in research and treatment?

While it is frequently argued that the government should not "legislate morality," the reality is that laws should – and generally do – follow ethical understanding. Society constantly creates laws to reflect and enforce collective moral norms. It is a commonplace assumption in our own society that if something is morally unacceptable (murder, battery, theft), then the law should outlaw it. (It is worthy of note that this parallelism between social mores and law is less true of positive moral responsibilities than it is of negative rights; we are far more likely to support a legal prohibition of murder than to pass a law requiring citizens to save a life whenever possible.) Thus, if it is morally impermissible to use stem cells, it probably should be legally impermissible to do so.

Another common objection to legal regulation of the use of stem cells is that the government should not interfere with scientific inquiry. The content of our discussions revealed that even if one believes that the creation of "research-purpose embryos" ought to be permissible, one must nevertheless admit that this is more than a simple question of research freedom. As one SCSG speaker put it, the treatment of embryos is a defining social practice, such as marriage, adoption, childrearing, child abuse, abortion and disposal of the dead. We do not consider it to be

inappropriate to be concerned as a polity (through our government) about the nature of our society as it is reflected in these practices, and neither should we disregard the implications of embryonic stem cell research.

E.2.a. Distinction between "permitting" and "facilitating"

When the government permits a practice – and particularly when that practice is ethically controversial – it may still choose not to materially support that practice. Here again, there is a clear preference for "negative" rights over their "positive" counterparts. In the United States, a woman may have a legal negative right to have an abortion, but she does not have a concomitant positive right to be assisted in that endeavor by the government. This distinction is the basis for President Bush's policy to withhold federal funding for obtaining stem cells, while allowing such research to continue in the private sector.

Often, the distinction between permitting and facilitating reflects considerations of federalism (i.e., the balance of authority between state governments and the national government). Every state government enjoys a broad "police power" to regulate for the benefit of public safety and welfare. When the original thirteen colonies agreed to yield some of their sovereignty and become states in the United States of America, they made the national government one of limited powers. Congress does not have a broad police power to protect public safety and welfare. Rather, it can enact laws only in accordance with the powers that are enumerated to it in the United States Constitution. Thus, while state governments have clear authority to ban stem cell research, the national government might not have such authority. The Constitution does not specifically authorize Congress to regulate in the area of health, so Congress has to justify its regulation of medical research and practice as a way to advance one of its other powers (e.g., its authority to regulate interstate commerce). Because the powers of Congress are limited, its only recourse to certain activities may be to withhold funding from them.

In addition to withholding funding to discourage a permitted activity, Congress can also discourage the activity by linking funding for other projects to the recipient's willingness to refrain from the activity in question. For example, although Congress cannot prohibit physicians from discussing the option of abortion with pregnant women, it can withhold funding from clinics whose physicians discuss abortions with the patients. Thus, Congress could prohibit recipients of Medicare or Medicaid funds from engaging in stem cell research.

Although the exact avenue of federal regulation may be uncertain, a majority of our group concluded that any regulation of stem cell research should be undertaken at the federal level of government and not at the state or local level. This conclusion reflected a number of considerations, most notably:

(1) Biomedical research and clinical facilities in the United States engage in and affect interstate and international commerce, which under the Constitution are regulated by the federal government. The services provided by clinical facilities move in interstate commerce, and patients travel regularly across state lines (and international borders) in order to access clinical facilities.

(2) Attempting to regulate what is clearly an international enterprise on a state-by-state basis can easily lead to confusion and conflict.

To be sure, there are important arguments for state regulation. In particular, when it is unclear how regulations should be written—should they prohibit stem cell research entirely or should they implement guidelines under which stem cell research is conducted?—it may be undesirable to

settle on a single approach for the entire country. States can try different approaches, allowing a "laboratory of state experimentation" that allows the country to discover by trial and error the optimal way to regulate stem cell research.

E.2.b. Deciding about permitting stem cell use

In addition to determining the moral weight to be granted the concerns about using stem cells, society also needs to decide how to resolve the conflict between differing and sometimes substantially opposing moral values. Does the moral equation take the form of balancing conflicting interests as in abortion? Under Supreme Court doctrine, the woman's interests prevail before viability when the fetus's interests are weaker, and the fetus's interests prevail after viability when those interests are greater. Instead of balancing conflicting interests, society might conclude that one interest always has greater weight, that it trumps the lesser interest. The "dead donor" rule in organ transplantation reflects this hierarchical approach. Physicians cannot take a life-necessary organ (e.g., a heart or whole liver) from a person for transplantation before the person is dead, even if the person is permanently unconscious and has left instructions in a living will for the use of the organs for transplantation in the event of permanent unconsciousness. A third approach to resolving conflicting interests is to identify other interests that tip the balance in one direction or another. This approach was used by the California Supreme Court in resolving a custody dispute in a case of gestational surrogacy (i.e., surrogacy in which a woman carries the pregnancy but doesn't supply the egg). The California court gave equal weight to the biological mother (the woman who supplied the egg) and the gestational mother (the woman who carried the pregnancy) but tipped the balance in favor of the biological mother because it had been the intent of both mothers that the biological mother would raise the child.

In addressing such challenges there is a strong temptation to draw analogies to abortion law, but such parallels are not necessarily decisive. On one hand, society might observe that an embryo in an infertility clinic has weaker interests than a fetus in a uterus. The embryo is younger and is not going to become a child if left alone. If a woman's right of self-determination allows her to end the life of a fetus in her uterus for no particular reason, then it seems to follow that an embryo in a laboratory can have its life ended for the good purpose of taking the stem cells to treat serious and irreversible illness. A right to abortion seems to perforce generate a right to take stem cells for therapeutic purposes. However, there is another way to apply abortion principles to stem cells. Although the embryo has weaker interests than the fetus, the possessor of an *ex utero* embryo has weaker interests than does a pregnant woman. The woman choosing abortion can be said to be acting not out of a general right of self-determination but out of a more particular right to restore her bodily integrity. Just as no parent is obligated to give bone marrow to a child for transplantation, so is no pregnant woman required to give of her body to maintain a fetus (until the fetus can survive without her body). Since an embryo in a laboratory invades no one's bodily integrity, it may be harder to justify its destruction than to justify the destruction of a fetus. In short, the applicability of the precedent of abortion law depends on *why* one believes abortion should be permissible.

F. Conclusions

Given wide (and seemingly irreconcilable) disagreement on a number of fundamental issues, the most important question facing policy-makers may well be how society ought to respond to such a diversity of perspectives. As we have described in the preceding sections, the diversity among Stem Cell Study Group members mirrored that of the wider public discourse, and complete agreement—especially on certain fundamental premises—was rarely, if ever, achieved.

Many in our group concluded that ES cell research is ethically permissible under certain conditions and that society ought to err in favor of its high moral duty to heal those who suffer from serious illness. From these ethical conclusions followed legal conclusions shared by the same group since it was conceded by all group members that the law should permit stem cell research to the extent that it is ethically permissible. These members supported ES cell research without the constraints of the Bush administration policy but under certain conditions:

(1) The research should be designed to develop treatments for serious diseases. Developing treatments for serious disease is a moral duty that may in some cases outweigh society's duty to treat embryos with respect. However, even if our duties to embryos are not equivalent to our duties to persons, we should not use them as a means to our own ends casually. Research that entails the destruction of embryos ought to be subject to rigorous standards for scientific necessity and therapeutic potential.

(2) The destruction of new embryos should not be undertaken unless the same research cannot be conducted using existing ES cell lines. This condition follows from the first condition. Since the destruction of embryos is only to be undertaken if it is strictly necessary for the treatment of serious disease, then researchers ought not to destroy additional embryos for ES cells if the same benefits can be realized from ES cells already in laboratories.

(3) Scientists should be allowed to create research-purpose embryos only if research cannot be adequately conducted on existing ES cell lines or on stem cells derived from embryos in excess of clinical need following infertility treatments.

As to the question of whether the government should not only permit stem cell research but also promote it through federal funding of research, those who considered ES cell research to be ethically permissible also believed that the federal government should provide funding for research on ES cells. Given the important benefits to be realized from the research and the greater ability of the government to regulate research it funds than to regulate privately funded research, federal funding can play an important role in this area. At the same time, those group members who considered ES cell research to be ethically unacceptable believed that the federal government should neither fund such research nor even allow it to proceed in the private sector. Significantly, all agreed that the ideal policy would be one that is rooted in the ethical acceptability or unacceptability of the research itself, and would therefore apply consistently to both the public and private sectors.

Most of all, in the implementation of these or any other policies related to stem cell research or other similarly divisive issues, the SCSG urges policy makers to be constantly mindful and respectful of the diversity of earnest and well-considered positions that can and should inform public policy. In this regard we agreed with NBAC that, "if it is possible to achieve essentially the same legitimate public goals with a policy that does not offend some citizens' sincere moral sensibilities, it would be better to do so" (NBAC 1999b, 57).

Listening to diverse perspectives

The SCSG experienced what many thoughtful groups before us have found: that coming to agreement on many of the issues related to human stem cell research is difficult. Part of the difficulty lies in competing views of what constitutes the greater moral good. This applies both to those whose beliefs derive from one of

the many faith traditions and to those whose views have more secular foundations. It also applies to those who hold differing views about the role that the law should play in such matters.

Like the SCSG, society as a whole may never reach consensus on the issue of stem cell research. The two recent national bioethics commissions found that unanimity was difficult to achieve on issues of this kind (NBAC 1997, 1999b; PCB 2002). Indeed, the search for universally acceptable, overriding criteria for judging public policy is likely to be disappointing. But perhaps unanimity is the wrong goal—and even though consensus will always be a fleeting and weak form of agreement, it does have certain advantages: agreeing to disagree, agreeing to respect the views of others, and agreeing to learn from diversity are every bit as valuable for informing public policy as finding final and unanimous agreement. On many issues—perhaps stem cell research among them—it seems that the traditional strategies for effecting resolution have proven inadequate, and there remains a pressing need for alternative ways of conceiving of and reconciling competing visions of the common good. Our limited exposure to the issues involved in stem cell research convinced us of the continuing resonance of political scientist Robert Dahl's classic insight:

> There is, then, an indispensable need in political analysis for the informed imagination; for speculation, guided by knowledge, that transcends the received truths; for the design and contemplation of Utopias; for a willingness to think hard about unthinkable alternatives to all the too easily thinkable solutions. There is, in short, a need for a creative search inspired by the hunch that somewhere between the unattainable best and the kind of mediocrity so often attained in political matters there lies a universe of better alternatives—and worse ones, too—all waiting to be explored. (Dahl 1976, 147)

It is in the pursuit of these important goals that we offer our efforts as one possible model for informed public discussion. Although the *content* of our discussion was always compelling, it sometimes seemed that the *process* was the more important aspect of the Stem Cell Study Group. Together, we skirted and then directly confronted difficult and seemingly irreconcilable perspectives. Yet the discussion remained a civil and respectful discourse among persons of conscience. As a group we modeled a process in which non-dominant voices and perspectives could be heard by mutually respectful colleagues, mindful of the values that we did share, and committed to the further exploration (together) of the duties and possibilities of public policy related to stem cell research. The "respected dissenters" helped to illuminate the boundaries, inconsistencies and possibilities of the more dominant positions. In the end, while we were not able to resolve all moral questions related to stem cell research (and we acknowledged that lack of resolution), we did come to a deeper understanding of the value of listening to diverse perspectives.

References

American Association for the Advancement of Science and Institute for Civil Society (AAAS/ICS). 1999. *Stem Cell Research and Applications: Monitoring the Frontiers of Biomedical Research*. November. Available from http://www.aaas.org/spp/sfrl/projects/stem/report.pdf.

American Journal of Bioethics (AJOB). 2002. Special Issue: Stem Cells. Vol. 2, No.1.

Blau HM, TR Brazelton and JM Weimann. 2001. The evolving concept of a stem cell: entity or function? *Cell* 105:829-841.

Burtchaell, JT. 1988. University policy on experimental use of aborted fetal tissue. *IRB* 10(4)7-11.

Cahill, LS. 2001. Religion and theology. In Sugarman J and D Sulmasy, *Methods in Medical Ethics*. Washington, DC: Georgetown University Press: 47-69.

Cooperman, A. 2002. Two Jewish groups back therapeutic cloning: Orthodox leaders break with right. *Washington Post*, March 13, A4.

Dahl, RA. 1976. *Modern Political Analysis*. 3rd ed. Englewood Cliffs, NJ: Prentice-Hall, Inc.

Dorff, EN. 2002. Embryonic stem cell research: the Jewish perspective. *The United Synagogue Review* (Spring):29-33.

———. 2000. Stem cell research. In NBAC, *Ethical Issues in Human Stem Cell Research, Volume III: Religious Perspectives*. Rockville, MD. C3-C5. Available from http://www.georgetown.edu/research/nrcbl/nbac/pubs.html.

Feldman, DM. 1986. *Health and Medicine in the Jewish Tradition*. New York: Crossroad.

Holden, C and G Vogel. 2002. Plasticity: time for a reappraisal? *Science* 296:2126-2129.

Howell, JC, MC Yoder and EF Srour. 2002. Hematopoietic potential of murine skeletal muscle-derived $CD45^{-}Sca\text{-}1^{+}c\text{-}kit^{-}$ cells. *Exp Hematol* 30:915-924.

Institute of Medicine (IOM). 2002. *Stem Cells and the Future of Regenerative Medicine*. Washington, DC: National Academy Press. Available from: http://www.nap.edu/books/0309076307/html/.

Jiang, Y, BN Jahagirdar, RL Reinhardt, et al. 2002. Pluripotency of mesenchymal stem cells derived from adult marrow. *Nature* 418:41-49.

Kukla, HJ. 2002. Embryonic stem cell research: an ethical justification. *Georgetown Law J* 90:503-543.

Lanza, RP, AL Caplan, LM Silver, et al. 2000. The ethical validity of using nuclear transfer in human transplantation. *JAMA* 284:3175-3179.

Lindblom, C and E Woodhouse. 1993. *The Policy-Making Process*. 3rd ed. Englewood Cliffs, NJ: Prentice Hall, Inc..

MacIntyre, A. 1981. *After Virtue*. Notre Dame: University of Notre Dame Press.

Moreno, JM, AL Caplan, PR Wolpe, et al. 1998. Updating protections for human subjects involved in research. *JAMA* 280:1951-1958.

National Bioethics Advisory Commission (NBAC). 1997. *Cloning Human Beings*. Rockville, MD. June. Available from http://www.georgetown.edu/research/nrcbl/nbac/pubs.html.

———. 1999a. *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance*. Rockville, MD. August. Available from http://www.georgetown.edu/research/nrcbl/nbac/pubs.html.

———. 1999b. *Ethical Issues in Human Stem Cell Research*. Rockville, MD. September. Available from http://www.georgetown.edu/research/nrcbl/nbac/pubs.html.

———. 2000. *Ethical Issues in Human Stem Cell Research, Volume III: Religious Perspectives*. Rockville, MD. June. Available from http://www.georgetown.edu/research/nrcbl/nbac/pubs.html.

National Institutes of Health (NIH). 2001. *Stem Cells: Scientific Progress and Future Research Directions*. Bethesda, MD. June. Available from http://www.nih.gov/news/stemcell/scireport.htm.

New York State Task Force on Life and the Law. 1998. *Assisted Reproductive Technologies: Analysis and Recommendations for Public Policy*. New York, NY. April.

Nuffield Council on Bioethics (NCB). 2001. *Stem cell therapy: the ethical issues* [Discussion Paper]. London. November 14. Available from http://www.nuffieldbioethics.org/publications/pp_0000000007.asp.

Orkin, SH. 2000. Stem cell alchemy. *Nat Med* 6(11):1212-1213.

Passeggio, ER. 2002. Embryonic stem cell research: shifting availability of federal funds. *Boston University Journal of Science & Technology Law* 8:347-352.

Pontifical Academy for Life. 2000. *Declaration on the Production and the Scientific and Therapeutic Use of Human Embryonic Stem Cells*. August 25. Available from http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20000824_cellule-staminali_en.html.

President's Council on Bioethics (PCB). 2002. *Human Cloning and Human Dignity: An Ethical Inquiry* [Pre-Publication Version]. Washington, DC. July. Available from http://www.bioethics.gov/cloningreport.

Rosner, F. 1978. The Jewish attitude toward abortion. In Kellner M, *Contemporary Jewish Ethics*. New York: Sanhedrin Press. 257-269.

Shamblott, MJ, J Axelman, S Wang, et al. 1998. Derivation of pluripotent stem cells from cultured human primordial germ cells. *Proc Natl Acad Sci USA* 95:13726-13731.

Shannon, TA and AB Wolter. 1990. Reflections on the moral status of the pre-embryo. *Theological Studies* 51:603-626.

Singer, PA, E Ambrosio, S Birenbaum, et al. 1992. Advance directives: are they an advance? *Canadian Medical Association Journal* 146:127-134.

Thomson, JA, J Itskovitz-Elder, SS Shapiro, et al. 1998. Embryonic stem cell lines derived from human blastocysts. *Science* 282:1145-1147.

University of Illinois at Chicago Research Ethics Study Group. 2002. "Doing it right – together": study groups & research agendas. *IRB: Ethics & Human Research*. 24(1):9-10.

The White House. 2001. *Fact Sheet: Embryonic Stem Cell Research* [Press Release]. August 9. Available from http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html.

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Appendix A: Speaker Schedule

30 January 2002 — *The Science of Stem Cells*

Mervin C. Yoder, M.D.
Professor of Pediatrics, Biochemistry and Molecular Biology
Indiana University School of Medicine

13 February 2002 — *Clinical Applications of Stem Cell Research*

Hal E. Broxmeyer, Ph.D.
Chairman and Mary Margaret Walther Professor of
Microbiology/Immunology
Professor of Medicine
Scientific Director, Walther Oncology Center
Indiana University School of Medicine

6 March 2002 — *Legal Issues Related to Stem Cell Research*

David Orentlicher, M.D., J.D.
Samuel R. Rosen Professor of Law
Co-Director, Center for Law and Health
Indiana University School of Law – Indianapolis
Core Faculty, Indiana University Center for Bioethics

10 April 2002 — *Stem Cell Research: Ethical and Policy Issues*

Eric M. Meslin, Ph.D.
Director, Indiana University Center for Bioethics
Professor of Medicine, Medical and Molecular Genetics
Indiana University School of Medicine
Professor of Philosophy
Indiana University School of Liberal Arts

16 April 2002 — *Theological Perspectives on Stem Cell Research*

Fr. Joe Rautenberg, Ph.D.
Ethicist, St. Vincent Hospital

Rabbi Dennis C. Sasso, D.Min., D.D.
Congregation Beth-El Zedeck

15 May 2002 — *Stem Cell Research in the Public and Private Sectors*

Steven H. Holtzman
President and CEO, Infinity Pharmaceuticals, Inc.
Commissioner, National Bioethics Advisory Commission, 1996-2000

Appendix B: Background Reading

Scientific Issues:

National Institutes of Health (NIH). 2001. *Stem Cells: Scientific Progress and Future Research Directions* [Executive Summary]. Bethesda, MD. June. Available from http://www.nih.gov/news/stemcell/scireport.htm.

Institute of Medicine (IOM). 2002. *Stem Cells and the Future of Regenerative Medicine*. Washington, DC: National Academy Press. Available from http://www.nap.edu/books/0309076307/html/.

Thomas, ED and R Storb. 1999. The development of the scientific foundation of hematopoietic cell transplantation based on animal and human studies. In Thomas, ED, KG Blume and SJ Forman, *Hematopoietic Cell Transplantation*. Oxford: Blackwell Science, Inc. 1-11.

Broxmeyer, HE and FO Smith. 1999. Cord blood stem cell transplantation. In Thomas, ED, KG Blume and SJ Forman, *Hematopoietic Cell Transplantation*. Oxford: Blackwell Science, Inc. 431-443.

Körbling M. 1999. Peripheral blood stem cells for allogeneic transplantation. In Thomas, ED, KG Blume and SJ Forman, *Hematopoietic Cell Transplantation*. Oxford: Blackwell Science, Inc. 469-480.

Legal Issues:

National Bioethics Advisory Commission (NBAC). 1999. Chapter 3: The legal framework for federal support of research to obtain and use stem cells. In NBAC, *Ethical Issues in Human Stem Cell Research*. Rockville, MD. September. 29-44. Available from http://www.georgetown.edu/research/nrcbl/nbac/pubs.html.

Ethical Issues:

NBAC. 1999. Chapter 4: Ethical issues in human stem cell research. In NBAC, *Ethical Issues in Human Stem Cell Research*. Rockville, MD. September. 45-63. Available from http://www.georgetown.edu/research/nrcbl/nbac/pubs.html.

Fletcher, JC. 2000. Deliberating incrementally on human pluripotent stem cell research. In NBAC, *Ethical Issues in Stem Cell Research*, *Volume II: Commissioned Papers*. Rockville, MD. January. E1–E50. Available from http://www.georgetown.edu/research/nrcbl/nbac/pubs.html.

Parens, E. 2000. What has the president asked of NBAC? On the ethics and politics of embryonic stem cell research. In NBAC, *Ethical Issues in Stem Cell Research*, *Volume II: Commissioned Papers*. Rockville, MD. January. I1–I12. Available from http://www.georgetown.edu/research/nrcbl/nbac/pubs.html.

Siegel, A. 2000. Ethics, public policy and human stem cell research. In NBAC, *Ethical Issues in Stem Cell Research*, *Volume II: Commissioned Papers*. Rockville, MD. January. J1–J11. Available from http://www.georgetown.edu/research/nrcbl/nbac/pubs.html.

Theological Issues:

Pontifical Academy for Life. 2000. *Declaration on the Production and the Scientific and Therapeutic Use of Human Embryonic Stem Cells*. August 25. Available from http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20000824_cellule-staminali_en.html.

Woodward, KL. 2001. A question of life or death: untangling the knottiest of ethical dilemmas. *Newsweek*. July 9.

The National Catholic Bioethics Center. 2000. Response to the draft National Institutes of Health guidelines for research involving human pluripotent stem cells (December 1999). *Ethics and Medics* 25(3).

Dorff, EN. 2002. Embryonic stem cell research: the Jewish perspective. *The United Synagogue Review* (Spring):29-33.

Cohen, CB. 2000. Open possibilities, close concerns: the import of religious views on the future of stem cell research. *The Park Ridge Center Bulletin* 13 (January).

Religious Views on Stem Cell Research [television interview with Lisa Sowle Cahill and Sondra Wheeler]. *Religion and Ethics Newsweekly*. Available from http://www.thirteen.org/religionandethics/week448/perspectives.html.

Hefner, P. 2000. The destiny and danger of being human. *Zygon* (October). Available from http://zygoncenter.org/hefnercloning2.htm

NBAC. 2000. *Ethical Issues in Human Stem Cell Research, Volume III: Religious Perspectives*. Rockville, MD. June. Available from http://www.georgetown.edu/research/nrcbl/nbac/pubs.html.

Porter, J. 2002. Is the embryo a person? *Commonweal* (February 8).

Harvey, JC. 2002. Distinctly human: the when, where & how of life's beginnings. *Commonweal* (February 8).

Miscellaneous:

Cibelli, JB, KA Grant, KB Chapman, et al. 2002. Parthenogenetic stem cells in nonhuman primates. *Science* 295:819.

Guterman, L. 2002. Scientists announce advances in research on adult and embryonic stem cells. *The Chronicle of Higher Education* (June 21).

Kolata, G. 2002. Hybrid embryo mixture may offer new source of stem cells for study. *The New York Times*, June 4, D3.

Leggett, K. 2002. Fertile ground: as West mulls ethics, China forges ahead in stem-cell research. *The Wall Street Journal*, 6 March.

McGee, G. 2002. Congress needs Biotech 101. February 15. Available from http://www.msnbc.com/modules/exports/ct_email.asp?/news/708379.asp.

Safire, W. 2002. On language: slippery slope. *The New York Times Magazine*, April 7, 24.

Wade, N. 2002. New stem cell source called possible. *The New York Times*, February 1.